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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/616,705 | 07/10/2003 | Mike Zeeff | MAR-021133 | 1561 |
| 30981 | 7590 | 01/25/2005 | EXAMINER | |
| King & Jovanovic, PLC 170 College Avenue SUITE 230 HOLLAND, MI 49423 | | | FERNSTROM, KURT | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3714 | |

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|--------------|--|
| Office Action Summary | Applicati n No. | Applicant(s) | |
| | 10/616,705 | ZEEFF, MIKE | |
| | Examin r | Art Unit | |
| | Kurt Fernstrom | 3712 | |

-- The MAILING DATE of this communication appears on th cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 contains the term "about", which renders the claim indefinite. Applicant is attempting to claim a range, without defining the boundaries of the range.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider in view of Iwamoto. Schneider discloses in column 3, line 43 to column 4, line 66 an artificial bone comprising a substrate material comprising a plurality of closed cells. Schneider fails to disclose a suppression component or an x-ray component. Iwamoto discloses in column 4, lines 13-20 a bone simulating material which includes an x-ray component dispersed therein. Iwamoto also discloses at

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column 1, line 30 that the material may be used to create an artificial bone. It would have been obvious to one of ordinary skill in the art to modify the device of Schneider by providing an x-ray component therein for the purpose of making the material detectable using an x-ray. With respect to claim 3, Schneider discloses the use of polyurethane. With respect to claim 5, Iwamoto discloses in column 4, line 19 the claimed percentage. With respect to claims 7 and 8, claim 1 does not positively recite that the invention comprises a suppression component. Therefore, claims 7 and 8 also fail to explicitly recite a suppression component, as they merely provide further limitations to one member of the Markush group of claim 1. Since Schneider as viewed with Iwamoto discloses the other member of the Markush group, they read on claims 7 and 8.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider in view of Iwamoto, and further in view of Miyata. Schneider as viewed in combination with Iwamoto discloses all of the limitations of the claims with the exception of the impregnation of a suppression component. Miyata discloses in column 3, lines 15-40 an artificial bone which is impregnated with collagen. This collagen is considered to be a suppression component, as it increases the strength of the bone, thus inherently reducing chipping and cracking. It would have been obvious to one of ordinary skill in the art to modify the device of Schneider as viewed in combination with Iwamoto by impregnating the bone with a suppression component for the purpose of increasing the strength of the artificial bone.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider in view of Iwamoto, and further in view of Biermann. Schneider as viewed in

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combination with Iwamoto discloses all of the limitations of the claims with the exception of the use of polyethylene. This material is known in the art, as disclosed for example in column 2, lines 33-66 of White. It would have been obvious to one of ordinary skill in the art to modify the device of Schneider as viewed in combination with Iwamoto by providing polyethylene for the purpose of creating a device which more closely resembles an actual human bone.

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider in view of Iwamoto, and further in view of White. Schneider as viewed in combination with Iwamoto discloses all of the limitations of the claims with the exception of the steps of placing the substrate material into a mold, curing it and finishing it. These steps are known in the art, as disclosed for example by White. It would have been obvious to one of ordinary skill in the art to modify the device of Schneider as viewed in combination with Iwamoto by providing the claimed steps for the purpose of creating a device which more closely resembles an actual human bone. With respect to claim 10, claim 9 does not positively recite that the invention comprises a suppression component. Therefore, claim 10 also fails to explicitly recite a suppression component, as it merely provide further limitations to one member of the Markush group of claim 9. Since Schneider as viewed with Iwamoto discloses the other member of the Markush group, they read on claim 10.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider in view of Iwamoto and White, and further in view of Miyata. Schneider as viewed in combination with Iwamoto and White discloses all of the limitations of the

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claim with the exception of the impregnation of a suppression component. Miyata discloses in column 3, lines 15-40 an artificial bone which is impregnated with collagen. This collagen is considered to be a suppression component, as it increases the strength of the bone, thus inherently reducing chipping and cracking. It would have been obvious to one of ordinary skill in the art to modify the device of Schneider as viewed in combination with Iwamoto and White by impregnating the bone with a suppression component for the purpose of increasing the strength of the artificial bone.

Response to Arguments

Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection. Because new grounds of rejection have been presented, this action is made non-final.

With respect to the rejections under 35 USC 112, "about" remains indefinite for the same reasons that "approximately" was previously rejected. There is no way to determine whether 9.9%, or 9%, or 5% would read on the claim language. See MPEP 2173.05(b). The arguments concerning the other rejections under 35 USC 112 are persuasive, and those rejections have been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kurt Fernstrom whose telephone number is (571) 272-4422. The examiner can normally be reached on M-F 9:30-6:00. If attempts to reach

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the examiner by telephone are unsuccessful, the examiner's supervisor, Derris Banks can be reached on (571) 272-4419. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KF
January 24, 2005



**KURT FERNSTROM
PRIMARY EXAMINER**